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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,798	10/12/2001	Ellen M. Heath	17094.002US1	7769

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EXAMINER	
OLSON, ERIC	
ART UNIT	PAPER NUMBER
1623	

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12/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/974,798	HEATH ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-32,34-36,38-43,45-59,61-63 and 65-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-32,34-36,38-43,45-59,61-63 and 65-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted September 15, 2008 wherein the rejections of record in the previous office action are traversed . This application was filed October 12, 2001 and makes no priority claims.

Claims 21-32, 34-36, 38-43, 45-59, 61-63, and 65-71 are pending in this application.

Claims 21-32, 34-36, 38-43, 45-59, 61-63, and 65-71 as amended are examined on the merits herein.

The following rejections of record in the previous office action are maintained:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-27, 30-32, 34-36, 38-40, 42, 43, 45-54, 57-59, 61-63, 65-67, and 69-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deggerdal et al. (PCT international publication WO96/18731, of record in previous office action) in view of Nargessi. (US patent 6855499, of record in previous action).

Deggerdal et al. discloses a method of isolating a nucleic acid, including RNA, by treating the nucleic acid with detergent and allowing it to bind to a solid support. (p. 5, paragraphs 2-4) The nucleic acid can be isolated from any material containing nucleic

acids, including the microorganisms, clinical samples, and environmental samples described in instant claims 23-26 (p. 6, paragraphs 2-3) and can include semi-pure materials as described in instant claim 21. The binding step can be preceded by a lysing step to lyse the biological material. (p. 6, last paragraph) Detergents suitable for use in this invention include any detergent, including non-ionic detergents. (p. 7, last paragraph) Additionally, a source of monovalent cations in a concentration of 0.1-1M can be included to increase nucleic acid capture (p. 8, second paragraph) along with a chelating agent such as EDTA. (p. 8, third paragraph) Several examples are provided of lysis solutions in which the monovalent cation is LiCl of up to 0.5M and the solution is buffered at pH 7.5, which is greater than 7. (p. 8, bottom of page) The solid support can be made of any well known solid support material, including non-silica materials such as glass, latex, or a polymeric material, and can be in various physical forms including tubes, plates, or wells. (p. 9, paragraphs 2-3) More than one solid support can be used. (p. 13, second paragraph) After the lysis and binding steps, washing and elution steps can be further performed to wash and isolate the nucleic acid. (p. 12, paragraphs 2-4) Examples are given in which all of the steps (a)-(e) of instant claim 21 are performed, for example, example 1 on p. 19. Binding is described to take place in a micorcentrifuge tube in example 6. (p. 23, lines 20-26)

Deggerdal et al. does not disclose a method in which lithium chloride is included in the lysis solution at a concentration of 4-10M or a method using cellulose as the solid support.

Nargessi discloses a method whereby nucleic acids are induced to absorb to a paramagnetic solid support such as paramagnetic cellulose-coated beads. (column 1, lines 45-52) Adsorption to solid support is facilitated by high concentrations of polyethylene glycol and salts. (column 1, lines 64-67) Salts useful in this method include various alkali and alkaline earth metal chlorides such as lithium chloride. (column 4, lines 8-12) Generally, the salt can be present in up to about 5M. (column 4 lines 19-20)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Deggerdal et al. by using a cellulose solid support for the purification and by adding 4-5M of lithium chloride to the lysis/binding buffer. One of ordinary skill in the art would have been motivated to modify the invention in this manner because Nargessi discloses that these concentrations of lithium chloride facilitate the binding of nucleic acid to the solid support, and because Nargessi explicitly suggests using cellulose as the solid support in the purification procedure. One of ordinary skill in the art would reasonably have expected success because adjusting the concentration of one component of a known mixture within the range disclosed by the prior art (i.e. choosing the upper range of 4-5M from the broad range of 0.25-5M) is within the ordinary and routine skill in the art. Moreover, the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05 [R-1].

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted September 15, 2008, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that neither cited reference teaches a concentration of above 4M of alkali metal salt. However, as discussed in the body of the rejection, where the claimed range overlaps the prior art there is a *prima facie* case of obviousness. Although Deggerdal et al. teaches salt concentrations well below 4M, the reference teaches those salt concentrations for the binding of nucleic acid to a generic solid phase which can be any of a number of materials. Nargessi et al. by contrast teaches higher salt concentrations up to 5M for the purpose of binding the nucleic acid to magnetizable cellulose, a specific solid phase that can be used in the methods of the invention. One of ordinary skill in the art would have recognized that in order to use magnetizable cellulose as the solid phase, the concentration of salt would have to be increased according to Nargessi et al. As regards the preferred embodiment of 1.25M salt concentration in Nargessi et al., according to MPEP 2123, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. See In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." See In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) 27 F.3d at 554, 31 USPQ2d at 1132.). 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

Applicant further argues that Nargessi et al. discloses examples using chaotropic salts such as guanidine HCl. However, the disclosure of guanidine HCl occurs only in the examples as an incidental part of the disclosure. Nargessi et al. uses Guanidine HCl in these examples because it is part of the general state of the art to use it in DNA lysis and binding compositions. It is not essential for binding the nucleic acid to the magnetizable cellulose, and the disclosure of Nargessi et al. does not disclose it as an essential ingredient. Deggerdal et al. by contrast teaches that the use of chaotropic agents such as guanidine HCl is disadvantageous and should be avoided. Therefore one of ordinary skill in the art when combining the two reference would use the magnetizable cellulose and the high salt concentrations of Nargessi et al. but not the guanidinium HCl which is disclosed as entirely optional and is discouraged by Deggerdal et al.

For these reasons the rejection is deemed proper and made **FINAL**.

Claims 41 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deggerdal et al. (PCT international publication WO96/18731, of record in previous office action) in view of Nargessi. (US patent 6855499, of record in previous action) as applied to claims 21-27, 30-32, 34-36, 38-40, 42, 43, 45-54, 57-59, 61-63, 65-67, and 69-71 above, and further in view of the Calbiochem 2000-2001 reagent catalog. (of record in previous action, herein referred to as Calbiochem) The disclosure of Deggerdal et al. in view of Nargessi is discussed above. Deggerdal et al. in view of

Nargessi does not disclose a method in which the detergent in the lysis buffer is a triton or tween detergent.

Calbiochem discloses various triton (octylphenoxypolyethoxyethanol, p. 541) and tween (polysorbate, polyoxyethylene sorbitan monolaurate, p. 546) nonionic detergents. These detergents are reasonably considered to fall within the scope of nonionic detergents included in the teaching of Deggerdal et al.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use triton or tween detergents in the lysis/binding solution of Deggerdal et al. in view of Nargessi. One of ordinary skill in the art would have been motivated to use these detergents because Deggerdal et al. already discloses that nonionic detergents in general can be used in the lysis buffer. One of ordinary skill in the art would reasonably have expected success because Deggerdal et al. teaches that any detergent can be used successfully, and selecting a particular detergent is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted September 15, 2008, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant's arguments are the same as those made against the rejection over Deggerdal et al. in view of Nargessi alone and are not found persuasive for the same reasons. Therefore the rejection is maintained and made **FINAL**.

Claims 28-29 and 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deggerdal et al. (PCT international publication WO96/18731, of record in previous office action) in view of Nargessi. (US patent 6855499, of record in previous action) as applied to claims 21-27, 30-32, 34-36, 38-40, 42, 43, 45-54, 57-59, 61-63, 65-67, and 69-71 above, and further in view of Heath et al. (PCT international publication WO99/39009, reference of record in previous action) The disclosure of Deggerdal et al. in view of Nargessi is discussed above. Deggerdal et al. in view of Nargessi does not disclose a method in which the solid support is one or more polyesters.

Heath et al. discloses reagents and methods that incorporate a solid support for purifying DNA from samples. (p. 8, lines 8-11) The solid support can be a number of different materials including polyester. (p. 9, lines 12-15) These polyester solid supports are reasonably considered to fall within the scope of solid supports included in the teaching of Deggerdal et al.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use one or more polyesters as the solid supports in the method of Deggerdal et al. in view of Nargessi. One of ordinary skill in the art would have been motivated to use polyesters because Deggerdal et al. already discloses that various solid supports in general can be used to adsorb RNA and Heath et al. specifically discloses that polyester can adsorb nucleic acids. One of ordinary skill in the art would reasonably have expected success because Deggerdal et al. teaches that any solid

support can be used successfully, and selecting a particular solid support is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted September 15, 2008, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant's arguments are the same as those made against the rejection over Deggerdal et al. in view of Nargessi alone and are not found persuasive for the same reasons. Therefore the rejection is maintained and made **FINAL**.

Claims 21-26, 30-32, 34-36, 38-40, 42, 43, 45-53, 57-59, 61-63, 65-67, and 69-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deggerdal et al. (PCT international publication WO96/18731, of record in previous office action) in view of Lader. (US patent 6204375, of record in previous action)

Deggerdal et al. discloses a method of isolating a nucleic acid, including RNA, by treating the nucleic acid with detergent and allowing it to bind to a solid support. (p. 5, paragraphs 2-4) The nucleic acid can be isolated from any material containing nucleic acids, including the microorganisms, clinical samples, and environmental samples described in instant claims 23-26 (p. 6, paragraphs 2-3) and can include semi-pure materials as described in instant claim 21. The binding step can be preceded by a lysing step to lyse the biological material. (p. 6, last paragraph) Detergents suitable for use in this invention include any detergent, including non-ionic detergents. (p. 7, last

paragraph) Additionally, a source of monovalent cations in a concentration of 0.1-1M can be included to increase nucleic acid capture (p. 8, second paragraph) along with a chelating agent such as EDTA. (p. 8, third paragraph) Several examples are provided of lysis solutions in which the monovalent cation is LiCl of up to 0.5M and the solution is buffered at pH 7.5, which is greater than 7. (p. 8, bottom of page) The solid support can be made of any well known solid support material, including non-silica materials such as glass, latex, or a polymeric material, and can be in various physical forms including tubes, plates, or wells. (p. 9, paragraphs 2-3) More than one solid support can be used. (p. 13, second paragraph) After the lysis and binding steps, washing and elution steps can be further performed to wash and isolate the nucleic acid. (p. 12, paragraphs 2-4) Examples are given in which all of the steps (a)-(e) of instant claim 21 are performed, for example, example 1 on p. 19. Binding is described to take place in a micorcentrifuge tube in example 6. (p. 23, lines 20-26) Deggerdal et al. does not disclose a method in which lithium chloride is included in the lysis solution at a concentration of 4-10M.

Lader discloses a method for preserving RNA in tissue fragments without freezing. (column 3 lines 23-33) This is accomplished by adding a medium containing a salt that precipitates RNA along with cellular protein, including lithium, sodium, or potassium sulfate or chloride. (column 3, lines 47-56, column 4 lines 1-8) The storage medium preferably contains a concentration of at least 20g/100 mL, which is at least 4.76M of lithium chloride, or higher concentrations such as 50g/100 mL, which is about 4.55M of lithium sulfate. (column 3, line 57 – column 4 line 8)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Deggerdal et al. by adding 4-5M or higher of lithium chloride or sulfate to the sample in order to preserve it between the moment of collection and the point at which it is bound to the solid support. One of ordinary skill in the art would have been motivated to modify the invention in this manner because Lader discloses that these high concentrations of lithium salts act to preserve the RNA in the sample. One of ordinary skill in the art would reasonably have expected success because the method of Lader is already shown to be useful for string RNA for the same type of isolation techniques discussed by Deggerdal et al.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted September 15, 2008, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that Lader teaches the high concentration for preserving RNA in biological samples while the present claims teach the use of a RNA-complexing salt. However, the purpose of the salt does not distinguish it from the prior art if the actual chemical identity of the salt is the same. The same salts (e.g. lithium or sodium chloride) are used both in the methods of Lader et al. and in the present claims. Therefore they are in fact the same whether the motivation for their use is to complex RNA for isolation or to preserve the RNA in a biological sample for a period of time before isolating it.

Applicant further argues that Lader discloses the use of guanidinium isothiocyanate in example 4. However, guanidinium isothiocyanate is used in this

example as part of a prior art RNA extraction protocol. Its use was not related to the preservation of RNA but to the later extraction of the RNA. One of ordinary skill in the art would only have added GITC to the solution if he or she planned to perform a GITC-based RNA extraction protocol. However, if one of ordinary skill in the art planned to use the extraction protocol of Deggerdal et al., no GITC would be included in keeping with the teaching of Deggerdal et al. that chaotropic salts are problematic and should be avoided.

Therefore the rejection is deemed proper and made **FINAL**.

Claims 41 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deggerdal et al. (PCT international publication WO96/18731, of record in previous office action) in view of Lader (US patent 6204375, of record in previous action) as applied to claims 21-26, 30-32, 34-36, 38-40, 42, 43, 45-53, 57-59, 61-63, 65-67, and 69-71 above, and further in view of the Calbiochem 2000-2001 reagent catalog. (of record in previous action, herein referred to as Calbiochem)

The disclosure of Deggerdal et al. in view of Lader is discussed above. Deggerdal et al. in view of Lader does not disclose a method in which the detergent in the lysis buffer is a triton or tween detergent.

Calbiochem discloses various triton (octylphenoxypolyethoxyethanol, p. 541) and tween (polysorbate, polyoxyethylene sorbitan monolaurate, p. 546) nonionic detergents. These detergents are reasonably considered to fall within the scope of nonionic detergents included in the teaching of Deggerdal et al.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use triton or tween detergents in the lysis/binding solution of Deggerdal et al. in view of Lader. One of ordinary skill in the art would have been motivated to use these detergents because Deggerdal et al. already discloses that nonionic detergents in general can be used in the lysis buffer. One of ordinary skill in the art would reasonably have expected success because Deggerdal et al. teaches that any detergent can be used successfully, and selecting a particular detergent is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted September 15, 2008, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant's arguments are the same as those made against the rejection over Deggerdal et al. in view of Lader alone and are not found persuasive for the same reasons. Therefore the rejection is maintained and made **FINAL**.

Claims 27-29 and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deggerdal et al. (PCT international publication WO96/18731, of record in previous office action) in view of Lader (US patent 6204375, of record in previous action) as applied to claims 21-26, 30-32, 34-36, 38-40, 42, 43, 45-53, 57-59, 61-63, 65-67, and 69-71 above, and further in view of Heath et al. (PCT international publication WO99/39009, reference of record in previous action) The disclosure of

Deggerdal et al. in view of Lader is discussed above. Deggerdal et al. in view of Lader does not disclose a method in which the solid support is one or more polyesters.

Heath et al. discloses reagents and methods that incorporate a solid support for purifying DNA from samples. (p. 8, lines 8-11) The solid support can be a number of different materials including polyester. (p. 9, lines 12-15) These polyester solid supports are reasonably considered to fall within the scope of solid supports included in the teaching of Deggerdal et al.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use one or more polyesters as the solid supports in the method of Deggerdal et al. in view of Lader. One of ordinary skill in the art would have been motivated to use polyesters because Deggerdal et al. already discloses that various solid supports in general can be used to adsorb RNA and Heath et al. specifically discloses that polyester can adsorb nucleic acids. One of ordinary skill in the art would reasonably have expected success because Deggerdal et al. teaches that any solid support can be used successfully, and selecting a particular solid support is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted September 15, 2008, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant's arguments are the same as those made against the rejection over Deggerdal et al. in view of Lader alone and are not

found persuasive for the same reasons. Therefore the rejection is maintained and made **FINAL**.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-32, 34-36, 38-43, 45-59, 61-63, and 65-71 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-85 of copending Application No. 11/589364. (not yet published, Cited in PTO-892, herein referred to as '364) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-85 of '364 cover the entire scope of the claimed invention. In particular, they include the same claimed limitations with the exception that the pH of the lysis solution is either below 4.5 or

above 7. For example claims 3-5 of '364, teach the same alkali metal salts as the claimed invention, claims 6-10 teach the same biological samples, claim 11 teaches the same solid supports, claim 19 teaches the same chelating agents, and claim 20 teaches the same limitation of substantially undegraded RNA. Note that while claim 1 of '364 does not mention a detergent, claims 21 and 29-31 do include a detergent in the lysis/binding buffer. Therefore the embodiment of '364 in which the pH is above 7 anticipates the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Argument: Applicant's arguments, submitted January 7, 2008, with respect to the above ground of rejection have been fully considered and not found to be persuasive to remove the rejection. Applicant states that a terminal disclaimer will be filed with respect to this application if the present application is found to be allowable. As no terminal disclaimer has been filed, the rejection is made **FINAL**.

Conclusion

No claims are allowed in this application. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
11/26/2008

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623